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Total Number of Pages in This Submission

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Filing Date	July 24, 2001
First Named Inventor	John Thomas ALLEN
Art Unit	1797
Examiner Name	Leigh McKane
Attorney Docket Number	26015-194/P71

ENCLOSURES (Check all that apply)

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Firm Name	Luce, Forward, Hamilton & Scripps, LLP		
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John Thomas ALLEN
Serial No.: 09/912,576
Filed: July 24, 2001
For: SYSTEM FOR, AND METHOD
OF, IRRADIATING ARTICLES

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) Group Art Unit: 1797
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) Examiner: Leigh. McKANE
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) Conf. No.: 6668
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San Diego, California
December 13, 2007

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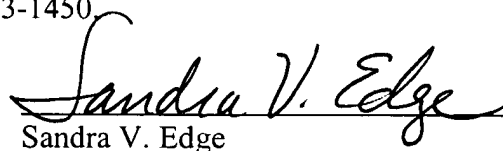
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Sandra V. Edge



26015-194/P71

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellants : John Thomas Allen *et al.*
Serial No. : 09/912,576
Confirmation No. : 6668
Filed : July 24, 2001
For : SYSTEM FOR, AND METHOD OF, IRRADIATING
ARTICLES
Group Art Unit : 1797
Examiner : Leigh McKane

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RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

Dear Sir or Madam:

In response to the Notification of Non-Compliant Appeal Brief dated November 27, 2007, applicant respectfully responds as follows: Amended Appellants' Brief is submitted concurrently herewith.

Although it is believed that no fees are due for this submission, the Commissioner is authorized to charge any fee required to our Deposit Account No. 50-0683, in the name of Luce, Forward, Hamilton & Scripps LLP.

Respectfully submitted,



December 13, 2007

Date

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26015-194/P71

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Group Art Unit : 1797
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Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDED APPEAL BRIEF

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Introduction

This brief is filed pursuant to 37 C.F.R. § 41.31 to appeal the Final Rejection dated January 8, 2007 of claims 1, 3, 4, 6, 7 and 9-52 of the above-identified patent application (“App.”).

(1) Real Party In Interest

The real party in interest in this proceeding is the assignee of the present application, The Titan Corporation, 3033 Science Park Road, San Diego, CA 92121¹. The Titan Corporation holds all right, title and interest in and to the present invention and pending application by virtue of an assignment dated August 8, 2005, recorded in the United States Patent and Trademark Office on September 8, 2005, at Reel 016500, beginning at Frame 0484; and an assignment dated August 8, 2005, recorded in the United States Patent and Trademark Office on September 8, 2005, at Reel 016500, beginning at Frame 0489.

(2) Related Appeals And Interferences

This application has not previously been before the Board of Patent Appeals and Interferences. Appellants’ undersigned representative is not aware of any related appeals and interferences within the meaning of 37 C.F.R. § 41.37(c)(1)(ii).

(3) Status Of Claims

Claims 1, 3, 4, 6, 7 and 9-52 are pending with claims 1, 4, 7, 10, 14, 17, 21, 25, 29, 32, 37, 43 and 46 being the independent claims. Claims 2, 5, 8 were previously cancelled.

Claims 1, 3, 4, 6, 7 and 9-52 were finally rejected in an Office Action mailed January 8, 2007. Claims 1, 3, 4, 6, 7, 9-15, 17-35 and 37-52 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over JP 2000312708 to Doi (“Doi”) in view of U.S. Patent No. 6,030,554 to Ichihara (“Ichihara”). Claims 16 and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Doi in view of Ichihara and in view of U.S. Patent No. 5,590,602 to Peck *et al.*

¹ Recently The Titan Corporation completed a merger with the surviving entity named “L-3 Communication Titan Corporation. This merger will be recorded with the USPTO assignment branch shortly.

Claims 1, 3, 4, 6, 7 and 9-52 are therefore on appeal. A copy of the claims on appeal can be found in the attached Appendix.

(4) Status Of The Amendments

No amendments were filed subsequent to the mailing of the final Office Action (“Office Action”) dated January 8, 2007.

(5) Summary Of The Claimed Subject Matter

The claims presently on appeal are drawn to a system and method of irradiating articles. The system and method utilize a fixture that is coupled to a closed container housing a plurality of articles and the fixture and closed container are moved past a radiation source to irradiate the articles. (App. at p. 1, lines 9-14; p. 8, line 10-15; p. 21, lines 1-2 and 13-15; and Figures 6 and 7.) The method of claim 1 comprises providing radiation from a radiation source (App. at p. 10, lines 10-11; p. 11, lines 10-11; and FIGS. 1-7); providing a closed container housing a plurality of articles in a predetermined configuration (App. at p. 20, lines 11-16; p. 22, lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); removably coupling a fixture to an external surface of the closed container (App. at p. 21, lines 1-2; FIGS. 6 and 7); and moving the closed container and fixture through the radiation from the radiation source (App. at p. 21, line 15 – p. 22, line 2; p. 22, lines 14-16; FIGS. 6 and 7). Claim 1 further recites that the fixture is coupled to the closed container such that when the closed container and fixture are moved through the radiation the fixture is located between the radiation source and the articles (FIGS. 6 and 7) and that the fixture has characteristics for absorbing radiation energy so that the radiation dose throughout the article is maintained between minimum and maximum limits (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12).

The method of claim 4 comprises providing radiation from a radiation source (App. at p. 10, lines 10-11; p. 11, lines 10-11; and FIGS. 1-7); providing a closed container including a plurality of articles in a predetermined configuration (App. at p. 20, lines 11-16; p. 22, lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); moving the articles in the closed container past the radiation (App. at p. 21, line 15 – p. 22, line 2; p. 22, lines 14-16; FIGS. 6 and 7); and providing for the absorption of the radiation energy from the source within particular minimum and maximum limits at different positions in the articles in the closed container (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12). Claim 4 further recites that the absorption of the radiation energy from the source within the minimum and maximum limits is controlled by a fixture having irregularities complementary at the different positions to irregularities of the article (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12) and the fixture being disposed external to the closed container (App. at p. 21, lines 1-2; FIGS. 6 and 7).

The method of claim 7 comprises providing radiation from a radiation source (App. at p. 10, lines 10-11; p. 11, lines 10-11; and FIGS. 1-7); providing a closed container including a plurality of articles in a predetermined configuration (App. at p. 20, lines 11-16; p. 22, lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); moving the articles past the radiation (App. at p. 21, line 15 – p. 22, line 2; p. 22, lines 14-16; FIGS. 6 and 7); and compensating outside of the closed container for the irregularities in the characteristics of the articles in the container to provide a uniformity in the radiation dose at the different positions in the articles within minimum and maximum limits (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12). Claim 7 further recites that the irregularities in the article at different positions result from irregularities in the dimension of the article (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12), the compensation is provided for the irregularities in the dimension of the article (App. at p. 19, line 7 – p. 20, line

1; p. 21, lines 3-12) and a fixture is disposed external to the closed container (App. at p. 21, lines 1-2; FIGS. 6 and 7).

The method of claim 10 comprises providing radiation from a radiation source (App. at p. 10, lines 10-11; p. 11, lines 10-11; and FIGS. 1-7); providing a closed container including a plurality of articles in the closed container held in a predetermined configuration (App. at p. 20, lines 11-16; p. 22, lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); providing a fixture outside of the closed container having irregular characteristics including at least one of irregular geometric shape and density to compensate for irregularities of the articles in the closed container (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12); disposing the fixture relative to the articles in the closed container (App. at p. 21, lines 1-2; FIGS. 6 and 7); moving the combination of the closed container and the fixture past the radiation source (App. at p. 21, line 15 – p. 22, line 2; p. 22, lines 14-16; FIGS. 6 and 7).

The method of claim 14 comprises providing radiation from a radiation source (App. at p. 10, lines 10-11; p. 11, lines 10-11; and FIGS. 1-7); providing a closed container including a plurality of articles held in a predetermined configuration (App. at p. 20, lines 11-16; p. 22, lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); providing a fixture having characteristics of absorbing at progressive positions in the fixture different doses of radiation per unit of distance of travel of the radiation through the fixture, the different doses of the radiation per unit of distance of the travel of the radiation through the fixture corresponding to the different doses of the radiation per unit of distance of travel of the radiation through the articles to maintain the exposure of the articles within minimum and maximum limits (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12); disposing the fixture external to the closed container and relative to the articles in the closed container (App. at p. 21, lines 1-2; FIGS. 6 and 7); moving the combination

of the closed container and the fixture at the progressive positions past the radiation from the radiation source to obtain the absorption by the articles within particular limits (App. at p. 21, line 15 – p. 22, line 2; p. 22, lines 14-16; FIGS. 6 and 7).

The method of claim 17 comprises providing radiation from a radiation source (App. at p. 10, lines 10-11; p. 11, lines 10-11; and FIGS. 1-7); providing a closed container including articles held in a predetermined configuration (App. at p. 20, lines 11-16; p. 22, lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); providing a fixture having at progressive positions characteristics, including at least one of the geometric shape and density, constituting a difference between substantially constant characteristics and the irregularities in the characteristics of the articles (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12); disposing the fixture exteriorly relative to the closed container to provide substantially constant characteristics for the combination of the articles in the closed container and the fixture at the progressive positions (App. at p. 21, lines 1-2; FIGS. 6 and 7); and moving the combination of the closed container and the fixture past the radiation from the source at the progressive positions (App. at p. 21, line 15 – p. 22, line 2; p. 22, lines 14-16; FIGS. 6 and 7).

The method of claim 21 comprises providing radiation from a radiation source (App. at p. 10, lines 10-11; p. 11, lines 10-11; and FIGS. 1-7); providing a closed container including articles held in a predetermined configuration (App. at p. 20, lines 11-16; p. 22, lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); providing a fixture with characteristics of absorbing the radiation corresponding to the characteristics of the articles to provide a substantially constant absorption in the articles in accordance with a difference between a substantially constant absorption and the absorption of the radiation by articles at the progressive positions (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12); disposing the fixture exteriorly of the closed

container to provide the substantially constant absorption at the progressive positions of the combination of each of the articles in the closed container and the fixture (App. at p. 21, lines 1-2; FIGS. 6 and 7); and moving the combination of the closed container and the fixture past the radiation (App. at p. 21, line 15 – p. 22, line 2; p. 22, lines 14-16; FIGS. 6 and 7).

The method of claim 25 comprises providing radiation from a radiation source (App. at p. 10, lines 10-11; p. 11, lines 10-11; and FIGS. 1-7); providing a closed container including articles held in a predetermined configuration (App. at p. 20, lines 11-16; p. 22, lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); providing a fixture having a composition with characteristics of absorbing the radiation corresponding to the absorption of the radiation by the at least one of the composition density and geometrical shape of the articles and having at progressive positions absorption characteristics compensating the absorption characteristics of the articles at progressive positions (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12); disposing the fixture outside of the closed container to provide the at least one of a substantially constant geometric shape, density and compensation between the combination of the articles and the fixture at progressive positions on the articles (App. at p. 21, lines 1-2; FIGS. 6 and 7); and moving the combination of the closed container and the fixture past the radiation from the source in a direction substantially perpendicular to the radiation from the source (App. at p. 21, line 15 – p. 22, line 2; p. 22, lines 14-16; FIGS. 6 and 7).

The system of claim 29 comprises a radiation source (App. at p. 10, lines 10-11; p. 11, lines 10-11; and FIGS. 1-7); a closed container including a plurality of articles held in a predetermined configuration each having irregularities in its characteristics at different positions in the article where the irregularities in the characteristics produce non-uniformities in the absorption or dosage in the article from the radiation source (App. at p. 20, lines 11-16; p. 22,

lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); a fixture disposed outside of the closed container and having characteristics of absorbing the radiation energy from the source at the different positions, to provide a substantial uniformity in the absorbed dosage at the different positions in the articles within minimum and maximum limits (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 1-12; FIGS. 6 and 7); and a conveyor for moving the closed container and the fixture past the radiation from the source (App. at p. 10, lines 14-15; p. 21, line 15 – p. 22, line 2; p. 22, lines 14-16).

The system of claim 32 comprises a radiation source (App. at p. 10, lines 10-11; p. 11, lines 10-11; and FIGS. 1-7); a closed container including a plurality of articles held in a predetermined configuration each having irregularities in its characteristics at different positions in the article where the irregularities in its characteristics affect the radiation dosage absorbed by the article at the different positions from the radiation source (App. at p. 20, lines 11-16; p. 22, lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); a fixture having irregularities in its characteristics to compensate for the irregularities in the characteristics of the articles (App. at p.), the fixture being disposed outside of the closed container (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 1-12; FIGS. 6 and 7); and a conveyor for moving the closed container and the fixture (App. at p. 10, lines 14-15; p. 21, line 15 – p. 22, line 2; p. 22, lines 14-16).

The system for receiving radiation in a particular direction from a radiation source of claim 37 comprises a closed container including a plurality of articles held in a predetermined configuration each having irregularities in its characteristics at different positions in the article where the irregularities in the characteristics of the article cause irregularities to be produced in the dosage received by the article from the radiation source at the different positions (App. at p. 20, lines 11-16; p. 22, lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); and a fixture

having irregularities in its characteristics at different positions in the fixture where the irregularities in the characteristics of the fixture cause the irregularities to be produced in the dosage received by the articles from the radiation source at the different positions, the irregularities in the characteristics of the fixture at the different positions complementing the irregularities in the characteristics of the articles at the different positions to provide a substantial uniformity in the dosage at the different positions in the articles within minimum and maximum limits (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12). Claim 37 further recites that the articles are disposed within the closed container and the fixture is disposed external to the closed container. (App. at p. 21, lines 1-2; FIGS. 6 and 7).

The system for receiving radiation from a radiation source of claim 43 comprises a closed container including a plurality of articles held in a predetermined configuration (App. at p. 20, lines 11-16; p. 22, lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); and a fixture disposed relative to the closed container and having irregularities in its characteristics for compensating for the irregularities in the characteristics in the articles in the closed container at the different positions in the articles to provide substantially a uniformity in the characteristics of the articles at the different positions within minimum and maximum limits (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12). Claim 43 further recites that the articles are disposed within the closed container and the fixture is disposed external to the closed container. (App. at p. 21, lines 1-2; FIGS. 6 and 7).

The system of claim 46 comprises a closed container (App. at p. 20, lines 11-16; p. 22, lines 3-6; p. 22, line 14 – p. 23, line 4; FIGS. 6 and 7); a plurality of articles disposed in the closed container such that they are held in a predetermined configuration to be irradiated (App. at p.), each of the articles having irregularities in its characteristics at progressive positions in the

articles in response to radiation (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 3-12); and a fixture disposed externally of the closed container and having irregularities in its characteristics at progressive positions in response to radiation to compensate for the irregularities in the characteristics of the articles in the closed container at the progressive positions (App. at p. 19, line 7 – p. 20, line 1; p. 21, lines 1-12; FIGS. 6 and 7).

(6) Grounds of Rejection to be Reviewed on Appeal

A. Whether claims 1, 3, 4, 6, 7, and 9-52 are rendered obvious by a combination of Doi and Ichihara.

B. Whether claims 16 and 36 are rendered obvious by a combination of Doi, Ichihara and Peck.

(7) Argument

(A) The Rejection under 35 U.S.C. § 103 based on Doi in view of Ichihara

Appellants respectfully submit that the pending claims patentably distinguish over the prior art relied upon in the final Office Action dated January 8, 2007, in which claims 1, 3, 4, 6, 7 and 9-15, 17-35 and 37-52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Doi in view of Ichihara. The Examiner states that Doi teaches a method and apparatus for electron beam sterilization of articles and that articles disclosed in Doi absorb radiation at different positions based on irregularities in the characteristics of the articles. The Examiner asserts that the lower half of component (10) in Figure 6A is a “container” and the upper half of components (10) is provided to absorb radiation passing from a source (20). The Examiner further reasons that “while Doi teaches two regulators 10 (wherein the bottom regulator also functions as a container for the articles) in Figures 6A and 6B, Doi is silent with respect to a

separate container for the articles, which container holds the articles and wherein the two regulators are disposed external to the container.”

The Examiner argues that Ichihara “discloses that ‘terminal sterilization,’ sterilizing an article within its final packaging, is known in the art in the field of electron beam sterilization.” The Examiner asserts that Ichihara discloses placing an article in a sealed container, which permits transmission of electron beam radiation, but prevents contamination by microorganisms so that after an article is sterilized it will not be contaminated during subsequent packaging and/or handling. The Examiner further asserts that it would have been obvious to package the articles of Doi prior to sterilization to prevent subsequent recontamination.

The Examiner also recognizes that Doi does not specifically disclose that the conveyor moves the articles at a substantially constant speed. However, the Examiner argues that it would have been obvious to do so in order to provide a uniform level of absorbed radiation throughout the article. Office Action at p.3, lines 18-22.

(i) The Doi Reference

Doi discloses an irradiation system that includes a source of an electron beam and a dose adjuster (10). Doi discloses embodiments that include the dose adjuster coupled to the irradiation source (Doi at ¶¶ 0023 and 0026; and FIGS. 4 and 5) and a dose adjuster that includes two halves that combine to form cavities that are configured to receive individual articles (Doi at ¶ 0026; and FIG. 6). In the first embodiments, the articles must be located precisely beneath the cavities of the dosage regulator so that a desired amount of irradiation is provided to the article. (Doi at ¶ 0023). The dosage regulator and article may or may not be moved toward each other prior to irradiation. (Doi at ¶ 0023) In the embodiment utilizing a dosage regulator

having two halves, an article is placed in each cavity of the dosage regulator prior to irradiation and the combined article and dosage regulator is irradiated. (Doi at ¶ 0026) .

Doi discloses that articles are stopped in position prior to being irradiated. Specifically, Doi discloses that when a dialyzer is correctly positioned with respect to the impression of the dosage regulator, the electron beam tube discharges an electron beam. (Doi at ¶ 0023) Furthermore, Doi discloses that by attaching the dosage regulator directly to the articles, the tolerance for positioning accuracy is reduced (Doi at ¶ 0026), but never discloses that the articles are carried past the radiation source at a constant speed.

(ii) The Ichihara Patent

Ichihara discloses a method of sterilizing an intraocular lens using an electron beam. The method includes sealing an intraocular lens in a sealed container and irradiating the intraocular lens. The sealed container is configured to allow the transmission of the electron beam while prohibiting the ingress of microorganisms.

Intraocular lenses are generally used in cataract surgery. (Ichihara at col. 1, line 17) In particular, a single intraocular lens is implanted into a human eye after the natural crystalline lens has been removed. (Ichihara at col. 1, lines 18-20) The process disclosed in Ichihara includes accommodating an intraocular lens in a sealed container that permits transmission of an electron beam therethrough; and irradiating the intraocular lens with the electron beam. (Ichihara at col. 2, lines 31-39; col. 10, lines 1-7) Ichihara states “only the dose of the electron beam is required to be controlled during the sterilizing treatment.” (Ichihara at col. 2, lines 44-45; col. 7, lines 5-7; col. 8, lines 7-14; and col. 12, lines 38-42).

(B) The Rejection under 35 U.S.C. § 103 over Doi in view of Ichihara and further in view of Peck

Appellants respectfully submit that the pending claims patentably distinguish over the prior art relied upon in the final Office Action dated January 8, 2007, in which claims 16 and 36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Doi in view of Ichihara and further in view of Peck. The Examiner recognizes that Doi is silent with respect to spacing adjacent containers and fixtures by a particular distance when they are moved past the radiation. The Examiner asserts that Peck teaches a method and apparatus for electron beam sterilization that includes articles conveyed within spaced containers.

(i) The Peck Patent

Peck discloses a conveyor system that includes a plurality of article carriers, a process conveyor for supporting and transporting the article carriers past the given location, an overhead power and free transport conveyor, and a load conveyor. (Peck at Abstract) Peck also discloses that the article carriers are positioned on the process conveyor so that there is a predetermined separation distance between adjacent article carriers. (Peck at Abstract). Peck does not disclose fixtures for regulating irradiation of articles.

(C) The Law of Obviousness

In order to establish a prima facie case of obviousness, three basic criteria must be met:

“First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined), must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the appellants’ disclosure.” M.P.E.P. § 2142.

The first requirement is that there must be some suggestion or motivation to combine the teachings of the references to create the claimed invention. The analysis does not require precise

teachings directed to the specific subject matter of the challenged claim, rather the analysis can find sufficient suggestion or motivation based on the inferences and creative steps that a person of ordinary skill in the art would employ. *KSR Int'l Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007). However, if a proposed modification renders the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification, because the prior art in effect teaches away from the modification. *In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed Cir. 1984).

In *Gordon*, claims drawn to a blood filter were rejected over a reference that disclosed a liquid strainer for removing dirt and water from gasoline and other light oils. The U.S. Patent and Trademark Board of Appeals (“Board”) affirmed the rejection of the Examiner asserting that it would have been obvious to turn the prior art liquid strainer upside down. *Id.* at 1126. The Court of Appeals for the Federal Circuit (“Federal Circuit”) reversed the Board’s decision after determining that turning the prior art liquid strainer upside down would render the strainer inoperable for its intended purpose. *Id.* at 1127. In particular, the gasoline to be filtered by the strainer would become trapped in a portion of the strainer and the water that the device was intended to separate out would flow freely out of the outlet of the strainer. *Id.* As a result, the Federal Circuit determined that “[i]n effect, [the prior art reference] teaches away from the board’s proposed modification.” *Id.*

The final requirement is that references when combined must teach or suggest all of the claim limitations. In other words, each claim limitation must be taught or suggested by at least one of the combined references. *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974). In *Royka*, the U.S. Court of Customs and Patent Appeals (“CCPA”) reversed an Examiner’s rejection under 35 U.S.C. § 103 because the references when combined did not teach or suggest each and every

limitation recited in the claim. *Id.* at 583. The CCPA determined that a rejection of the independent claim as being anticipated by the cited reference failed because the reference did not teach each and every limitation recited in the claim. *Id.* In considering a rejection of the dependent claims for obviousness, the court determined that the limitations missing from the initial references were also missing in the secondary reference. *Id.* Accordingly, the court reversed the obviousness rejection. *Id.*

(D) Application of the Law of Obviousness

(i) Claims 1, 3, 4, 7, 9-11, 13, 14, 17-34 and 36-52

The rejection of claims 1, 4, 7, 10, 14, 17, 21, 25, 29, 32, 37, 43 and 46 as being obvious over a combination of Doi and Ichihara is improper because the references fail to disclose all of the recited features. The Examiner asserts that Doi discloses all of the features recited in the independent claims except Doi is silent with respect to a separate container for the articles, which container holds the articles and wherein the two regulators are disposed external to the container. In order to fill these gaps in Doi the Examiner relies on Ichihara. The Examiner argues that Ichihara discloses “terminal sterilization” it would have been obvious to package the articles of Doi prior to sterilization. See Office Action, p. 3, lines 13-15.

As stated by the Examiner, Doi does not disclose a separate container for multiple articles and a radiation regulator that disposed external to the container. Ichihara also fails to disclose that feature. Ichihara describes sterilization of an intraocular lens after packaging but there is absolutely no disclosure in Ichihara of disposing a fixture external of the packaging that regulates the irradiation. In fact, Ichihara stresses that controlling the intensity of the electron beam is the only aspect that need be controlled in order to provide sufficient irradiation.

Furthermore, there is no disclosure in either reference of a closed container that houses a plurality of articles in a predetermined configuration. In the present invention, the closed container holds the articles in a predetermined configuration so that the radiation regulating fixture may be disposed external to the closed container while still corresponding to irregularities in the articles.

The Examiner argues that the lower half of the dosage regulator of Doi is a “container” and the upper half of the dosage regulator is a fixture. However, the lower half of the dosage regulator is not a closed container and in order for the dosage regulator to be a closed container, the upper half would have to be used in combination. The addition of the upper half of the dosage regulator would obviate the need for a fixture disposed external to the closed container.

Furthermore, the present invention specifically teaches the advantages of disposing a fixture external of a closed container. In particular, with regard to FIGS. 3-5 of the present application, because the lower areas of the fixtures extend into the space between articles, it prevents the articles from being boxed, but it is desirable to irradiate the articles after they have been boxed.

Even if a person having ordinary skill in the art were to find motivation to combine the teachings of Doi with the concept of terminal sterilization, that would not achieve the present invention. In particular, Doi teaches that the articles are enclosed by the regulator so that a single article is in each cavity. At most, combining that teaching with Doi would result in placing a single packaged article within a cavity of the regulator. It would not result in packaging a plurality of articles in a closed container in a predetermined configuration and disposing a fixture external of the closed container.

Because the combined teachings of Doi and Ichihara fail to disclose all of the features recited in independent claims 1, 4, 7, 10, 14, 17, 21, 25, 29, 32, 37, 43 and 46, those claims are patentable over Doi and Ichihara.

Claim 3 depends from and includes all of the features recited in claim 1 and for at least the same reasons is patentable over Doi and Ichihara. Claim 9 depends from and includes all of the features recited in claim 7 and for at least the same reasons is patentable over Doi and Ichihara. Claims 11 and 13 depend from and include all of the features recited in claim 10 and for at least the same reasons are patentable over Doi and Ichihara. Claims 18-20 depend from and include all of the features recited in claim 17 and for at least the same reasons are patentable over Doi and Ichihara. Claims 22-24 depend from and include all of the features recited in claim 21 and for at least the same reasons are patentable over Doi and Ichihara. Claims 26-28 depend from and include all of the features recited in claim 25 and for at least the same reasons are patentable over Doi and Ichihara. Claims 30 and 31 depend from and include all of the features of claim 29 and for at least the same reasons are patentable over Doi and Ichihara. Claims 33, 34 and 36 depend from and include all of the features recited in claim 32 and for at least the same reasons are patentable over Doi and Ichihara. Claims 38-42 depend from and include all of the features recited in claim 37 and for at least the same reasons are patentable over Doi and Ichihara. Claims 44 and 45 depend from and include all of the features recited in claim 43 and for at least the same reasons are patentable over Doi and Ichihara. Claims 47-52 depend from and include all of the features recited in claim 46 and for at least the same reasons are patentable over Doi and Ichihara.

(ii) Claims 6, 12, 15, 16 and 35

In addition to the reasons described above with respect to claims 4, 10, 14 and 32, claims 6, 12, 15 and 35 are patentable over Doi and Ichihara because the combined references fail to disclose moving the articles past the radiation source at a constant speed. Ichihara discloses that the electron beam is activated after the dialyzers are positioned correctly with respect to the dosage regulator that is coupled to the radiation source. As a result, it is clear that the dialyzers are stopped relative to the radiation source prior to irradiation. Ichihara also discloses enclosing the dialyzers with dosage regulator prior to irradiation and teaches that accuracy of the position of the dialyzers relative to the radiation source is less critical in such an embodiment. That disclosure, however, does not indicate or suggest that the dialyzers are moved past the radiation source at a constant speed. It merely indicates that the stopped position of the dialyzers does not have to be as accurate. Additionally, Ichihara does not disclose a conveyor system that moves the intraocular lenses past a radiation source at constant speed.

Because the combined references fail to disclose all of the recited features, claims 6, 12, 15 and 35 are patentable over Doi and Ichihara. Claim 16 depends from and includes all of the features recited in claim 15 and for at least the same reasons is patentable over Doi and Ichihara.

Conclusion

In view of the foregoing, appellants respectfully submit that the pending claims patentably distinguish over the prior art. Appellants respectfully request that the rejection under 35 U.S.C. §103(a) be reversed and that the above-identified application be passed to issue.

The Commissioner is authorized to charge any additional fee required, or credit any overpayment, to our Deposit Account No. 50-0683, in the name of Luce, Forward, Hamilton & Scripps LLP.

Dated: December 13, 2007

Respectfully submitted,



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Claims Appendix

1. A method of irradiating an article from a radiation source where the article absorbs the radiation at different positions in the article in accordance with irregularities in the characteristics of the article at the different positions, including the steps of:

providing radiation from the source in a particular direction,

providing a closed container housing a plurality of articles in a predetermined configuration,

removably coupling a fixture to an external surface of the closed container; and

moving the closed container and fixture through the radiation from the source in a direction transverse to the particular direction such that radiation energy passing from the source is absorbed by the articles,

wherein the fixture is coupled to the closed container such that when the closed container and fixture are moved through the radiation the fixture is located between the radiation source and the articles;

wherein the fixture has characteristics for absorbing the radiation energy such that the radiation dose at different positions in each article is maintained within particular minimum and maximum limits despite irregularities in the characteristics of the article at the different positions.

2. (Canceled)

3. A method as set forth in claim 1 wherein

the articles in the closed container are moved past the radiation from the source in a direction substantially perpendicular to the particular direction and wherein

the articles have at least one of an irregular configuration and density and the fixture has at least one of a configuration and density which, when combined with the at least one of the configuration and density of the articles in the closed container, provides at least one of a regular configuration and density.

4. A method of irradiating articles from a radiation source where the articles absorb the radiation from the source at different positions in the articles in accordance with irregularities in the characteristics of the articles at the different positions, including the steps of:

providing radiation from the source in a particular direction,

providing a closed container including a plurality of articles held in a predetermined configuration,

moving the articles in the closed container past the radiation from the source in a second direction transverse to the particular direction, and

providing for the absorption of the radiation energy from the source within particular minimum and maximum limits at the different positions in the articles in the closed container regardless of the irregularities in the characteristics of the articles at the different positions,

wherein the absorption of the radiation energy from the source within the particular minimum and maximum limits is controlled by a fixture having irregularities complementary at the different positions to the irregularities provided by the article at the different positions,

wherein the articles are disposed within the closed container and the fixture is disposed external to the closed container.

5. (Canceled)

6. A method as set forth in claim 4 wherein

the articles are conveyed past the radiation source in a direction substantially perpendicular to the particular direction and at a substantially constant speed.

7. A method of irradiating articles from a radiation source where the articles absorb the irradiation from the source at different positions in the articles in accordance with irregularities in the characteristics of the articles at the different positions, including the steps of:

providing radiation from the source in a particular direction,

providing a closed container including a plurality of articles held in a predetermined configuration,

moving the articles past the radiation from the source in a second direction substantially perpendicular to the particular direction, and

compensating outside of the closed container for the irregularities in the characteristics of the articles in the closed container at the different positions in the article to provide a uniformity in the radiation dose at the different positions in the articles in the closed container within particular minimum and maximum limits,

wherein the irregularities in the article at the different positions result from irregularities in the dimension of the article in the particular direction at the different positions,

wherein the compensation is provided for the irregularities in the dimension of the article in the particular direction at the different positions,

wherein the articles are disposed within the closed container and the fixture is disposed external to the closed container.

8. (Canceled)

9. A method as set forth in claim 7 wherein

the article is conveyed past the radiation from the source in a direction substantially perpendicular to the particular direction.

10. A method of irradiating an article from a radiation source where the article has irregular characteristics including at least one of an irregular geometrical shape and density and absorbs radiation passing through the article by an amount depending upon the irregular characteristics, including the at least one of the irregular geometrical shape and density, of the article and where the article has different absorption characteristics to radiation at progressive positions in the article, including the steps of:

providing the radiation from the radiation source in a first direction,

providing a closed container including a plurality of articles inside the closed container held in a predetermined configuration,

providing outside of the closed container a fixture having irregular characteristics, including at least one of an irregular geometric shape and density, at progressive positions to compensate for the differences in the irregularities of the characteristics, including irregularities in the at least one of the geometric shape and density, of the articles in the closed container at the progressive positions,

disposing the fixture relative to the articles in the closed container to provide the combination of the articles and the fixture with the compensating characteristics at the progressive positions in response to the radiation, and

moving the combination of the closed container and the fixture at the progressive positions past the radiation source to irradiate the articles in the closed container at the progressive positions.

11. A method as set forth in claim 10 wherein

the fixture has irregular characteristics at progressive positions, depending upon the irregularities in the characteristics of the articles in the closed container at the progressive positions, to compensate for the irregularities in the characteristics of the articles at the progressive positions.

12. A method as set forth in claim 10 wherein

the combination of the closed container and the fixture is moved past the radiation from the radiation source at a substantially constant speed in a direction substantially perpendicular to the direction of the radiation.

13. A method as set forth in claim 10 wherein

the fixture is made from a material selected from a group consisting of a plastic and a metal and having characteristics of absorbing the radiation substantially corresponding to the characteristics of the article in the closed container in absorbing the radiation.

14. A method of irradiating articles from a radiation source where the articles have characteristics of absorbing at progressive positions different doses of radiation per unit of distance of travel of radiation through the article, including the steps of:

providing radiation in a particular direction from the source,

providing a closed container including a plurality of articles held in a predetermined configuration,

providing a fixture having characteristics of absorbing at progressive positions in the fixture different doses of radiation per unit of distance of travel of the radiation through the fixture, the different doses of the radiation per unit of distance of the travel of the radiation through the fixture corresponding to the different doses of the radiation per unit of distance of

travel of the radiation through the articles to maintain within particular minimum and maximum limits at the progressive positions the amount of radiation received by the article per unit of travel of the radiation through the article,

disposing the fixture external to the closed container and relative to the articles in the closed container to maintain within particular limits at the progressive positions the dose of radiation received by the articles per unit of distance of travel of the radiation through the articles, and

moving the combination of the closed container and the fixture at the progressive positions past the radiation from the radiation source to obtain the absorption by the articles of the radiation from the source within the particular limits at the progressive positions in the articles.

15. A method as set forth in claim 14 wherein

the combination of the closed container and the fixture is moved past the radiation from the radiation source at a substantially constant speed in a direction substantially perpendicular to the direction of the radiation from the source.

16. A method as set forth in claim 15 wherein

each of the containers and each of the associated fixtures is spaced from the adjacent containers and fixtures by a particular distance within particular limits when the containers and the associated fixtures are moved past the radiation from the source.

17. A method of irradiating articles from a radiation source where the articles absorb radiation passing through the article by a dosage depending upon irregularities in the characteristics, including irregularities in the at least one of the geometric shape and density, of

the articles and where the articles have different absorption characteristics to radiation at progressive positions in the articles, including the steps of:

- providing the radiation from the radiation source in a first direction,
- providing a closed container including the articles held in a predetermined configuration,
- providing a fixture having at the progressive positions characteristics, including at least one of the geometric shape and density, constituting a difference between substantially constant characteristics and the irregularities in the characteristics of the articles in the closed container at the progressive positions,
- disposing the fixture exteriorly relative to the closed container to provide the substantially constant characteristics for the combination of the articles in the closed container and the fixture at the progressive positions, and
- moving the combination of the closed container and the fixture past the radiation from the source at the progressive positions.

18. A method as set forth in claim 17 wherein
the combination of the closed container and the article are moved past the radiation from the source in a second direction substantially perpendicular to the first direction.

19. A method as set forth in claim 17 wherein
the articles have irregularities in at least one of the dimension and the density of the fixture in the first direction at the progressive positions and wherein
the fixture has irregularities in the at least one of the dimension and density of the articles in the first direction at the progressive positions to provide a substantially constant dimension in the first direction at the progressive positions when the at least one of the dimensions and density of the article and the fixture in the first direction at the progressive positions are combined.

20. A method as set forth in claim 17 wherein

the progressive positions in the articles in the closed container and in the fixture are in a direction substantially perpendicular to the first direction.

21. A method of irradiating articles from a radiation source where the articles absorb radiation passing through the articles by a dosage depending upon the characteristics, including at least one of the geometric shape and the density, of the articles and where the articles have different absorption characteristics to radiation at progressive positions in the articles, including the steps of:

providing the radiation from the radiation source in a first direction,

providing a closed container including the articles held in a predetermined configuration,

providing a fixture with characteristics of absorbing the radiation corresponding to the characteristics of the articles to provide a substantially constant absorption in the articles in accordance with a difference between a substantially constant absorption and the absorption of the radiation by the articles at the progressive positions,

disposing the fixture exteriorly of the closed container to provide the substantially constant absorption at the progressive positions of the combination of each of the articles in the closed container and the fixture, and

moving the combination of the closed container and the fixture past the radiation from the source in a direction substantially perpendicular to the first direction.

22. A method as set forth in claim 21 wherein

the characteristics in the articles include the at least one of the geometrical shape and density of the articles and wherein the characteristics in the fixture include the at least one of the geometrical shape and density of the fixture and wherein

the at least one of the geometrical shape and density of the fixture provides the difference between the substantially constant characteristics and the irregularities in the at least one of the geometric shape of the articles in the closed container at the progressive positions.

23. A method as set forth in claim 21 wherein

the fixture includes two (2) fixture portions respectively disposed exteriorly of the closed container on the opposite sides of the closed container in the direction of the radiation from the source.

24. A method as set forth in claim 21 wherein

the fixture includes a single fixture having at least one of the a geometrical shape and density providing the difference between the substantially constant characteristics and the irregularities in the articles in the closed container at the opposite sides of the articles.

25. A method of irradiating articles from a radiation source where the articles absorb radiation by a dosage depending upon the characteristics of the articles and where the articles have different absorption characteristics to the radiation at progressive positions in the articles, the absorption of the radiation in the articles being dependent upon the at least one of the composition and geometric shape and density of the articles, including the steps of:

providing the radiation from the source in a particular direction,

providing a closed container including the articles held in a predetermined configuration,

providing a fixture having a composition with characteristics of absorbing the radiation corresponding to the absorption of the radiation by the at least one of the composition density

and geometrical shape of the articles and having at progressive positions absorption characteristics compensating the absorption characteristics of the articles at the progressive positions,

disposing the fixture outside of the closed container to provide the at least one of a substantially constant geometric shape, density and composition between the combination of the articles and the fixture at progressive positions on the articles, and

moving the combination of the closed container and the fixture past the radiation from the source in a direction substantially perpendicular to the radiation from the source.

26. A method as set forth in claim 25 wherein

the articles are provided with irregularities in at least one of their geometric shape, composition and density and wherein

the fixture is provided with irregularities in the at least one of its geometric shape, composition and density and wherein

the irregularities in the at least one of the geometric shape, density and composition of the fixture at the progressive positions are complementary to the at least one of the irregularities in the geometric shape, density and compositions of the articles at the progressive positions.

27. A method as set forth in claim 26 wherein

the irregularities in the at least one of the geometric shape, density and composition of the articles are disposed on the opposite sides of the articles in the direction of the radiation from the source.

28. A method as set forth in claim 25 wherein

the irregularities in the at least one of the geometric shape, composition and density of the fixture are disposed on a single side of the articles in the direction of the radiation from the source.

29. In combination,

a radiation source for providing radiation in a particular direction,

a closed container including a plurality of articles held in a predetermined configuration each having irregularities in its characteristics at different positions in the article where the irregularities in the characteristics produce non-uniformities in the absorption or dosage in the article from the radiation source,

a fixture disposed outside of the closed container and having characteristics of absorbing the radiation energy from the source at the different positions, relative to the irregularities in the absorption by the articles at the different positions, to provide a substantial uniformity in the absorbed dosage at the different positions in the articles within particular minimum and maximum limits, and

a conveyor for moving the closed container and the fixture past the radiation from the source in a direction perpendicular to the particular direction.

30. In a combination as set forth in claim 29 wherein

the irregularities in the characteristics of the articles include irregularities at least one of in the geometrical shape, density and composition of the articles and wherein

the irregularities in the characteristics of the fixture include irregularities in the at least one of the geometrical shape, density and composition of the fixture.

31. In a combination as set forth in claim 29 wherein

the combination of the irregularities in the at least one of the geometrical shape, density and composition of the articles and the irregularities in the at least one of fixture provide at least one of the substantially constant geometrical shapes, density and composition of the articles within particular minimum and maximum limits.

32. In combination,

a radiation source for providing radiation in a particular direction,

a closed container including a plurality of articles held in a predetermined configuration each having irregularities in its characteristics at different positions in the article where the irregularities in its characteristics affect the radiation dosage absorbed by the article at the different positions from the radiation source,

a fixture having irregularities in its characteristics to compensate for the irregularities in the characteristics of the articles, the fixture being disposed outside of the closed container, and

a conveyor for moving the closed container and the fixture in a direction substantially perpendicular to the particular direction.

33. In a combination as set forth in claim 32 wherein

the irregularities in the characteristics of the articles constitute at least irregularities in the at least one of the geometrical shapes, density and composition of the articles and wherein

the irregularities in the characteristics of the fixture constitute irregularities in at least one of the geometrical shapes, density and composition of the fixture.

34. In a combination as set forth in claim 32 wherein

the irregularities in the at least one of the geometrical shape, density and composition of the article constitute irregularities in at least one of the dimension, density and composition of the article in the direction of the radiation from the source and wherein

the irregularities in the at least one of the geometrical shape, density and composition of the fixture constitute irregularities in the at least one of the dimension. density and composition of the fixture in the direction of the radiation from the source.

35. In a combination as set forth in claim 32 wherein

the closed container is moved past the radiation from the source at a substantially constant speed within particular limits

36. In a combination as set forth in claim 32 wherein

the closed container is one of a sequence of closed containers and wherein the fixture is one of a sequence of fixtures and wherein the closed containers and the fixtures are moved in sequence past the radiation from the source at a substantially constant speed within particular limits and wherein

the closed containers and the fixtures are moved in sequence past the radiation from the source with a minimal separation between the closed containers within particular limits.

37. In combination for receiving radiation in a particular direction from a radiation source,

a closed container including a plurality of articles held in a predetermined configuration each having irregularities in its characteristics at different positions in the article where the irregularities in the characteristics of the article cause irregularities to be produced in the dosage received by the article from the radiation source at the different positions, and

a fixture having irregularities in its characteristics at different positions in the fixture where the irregularities in the characteristics of the fixture cause irregularities to be produced in the dosage received by the articles from the radiation source at the different positions, the irregularities in the characteristics of the fixture at the different positions complementing the irregularities in the characteristics of the articles at the different positions to provide a substantial uniformity in the dosage at the different positions in the articles within particular minimum and maximum limits,

wherein the articles are disposed within the closed container and the fixture is disposed external to the closed container.

38. In a combination as set forth in claim 37,

the fixture and the articles being movable past the radiation from the source to receive radiation from the source.

39. In a combination as set forth in claim 37,

the fixture including a first fixture portion on one side of the articles and a second fixture portion on the opposite side of the articles, the first and second fixture portions being separated

from each other, and the closed container being disposed between the fixtures in a direction corresponding to the direction of the radiation from the source.

40. In a combination as set forth in claim 38,

the articles having irregularities in its characteristics at the different positions on opposite sides of the articles and the fixture being provided with irregularities in its characteristics at the opposite sides of the closed container to compensate for the irregularities in the characteristics of the articles and to provide substantially the uniformity in the radiation dosage at the different positions in the articles within the particular minimum and maximum limits.

41. In a combination as set forth in claim 37,

the fixture being disposed on one side of the closed container and being provided with irregularities in its characteristics to compensate for the irregularities in the characteristics of the articles on the opposite sides of the articles and to provide substantially the uniformity in the radiation dosage at the different positions in the articles within the particular minimum and maximum limits.

42. In a combination as set forth in claim 37,

the fixture including a first fixture portion on one of the opposite sides of the articles and including a second fixture portion on the other of the opposite sides of the articles, the first fixture portion having irregularities in its characteristics to compensate for the irregularities in the characteristics of the articles on the one of the opposite sides of the articles and the second fixture portion having irregularities in the characteristics of the articles on the other of the

opposite sides of the articles to compensate for the irregularities in the articles on the other of the opposite sides of the articles.

43. In combination for receiving radiation in a particular direction from a radiation source,

a closed container including a plurality of articles held in a predetermined configuration each having irregularities in its characteristics at different positions in the articles, and

a fixture disposed relative to the closed container and having irregularities in its characteristics for compensating for the irregularities in the characteristics in the articles in the closed container at the different positions in the articles to provide substantially a uniformity in the characteristics of the articles at the different positions within particular minimum and maximum limits,

wherein the articles are disposed within the closed container and the fixture is disposed external to the closed container.

44. In a combination as set forth in claim 43,

the closed container and the fixture being disposed relative to the radiation source to provide for the passage of the radiation from the source through the articles in the closed container and the fixture.

45. In a combination as set forth in claim 43,

the irregularities in the characteristics of the articles constituting at least irregularities in at least one of the geometrical shape, density and composition of the articles and the

irregularities in the characteristics of the fixture constituting irregularities in at least one of the geometrical shape, density and characteristics of the fixture.

46. In combination,

a closed container,

a plurality of articles disposed in the closed container such that they are held in a predetermined configuration to be irradiated, each of the articles having irregularities in its characteristics at progressive positions in the articles in response to radiation, and

a fixture disposed externally of the closed container and having irregularities in its characteristics at progressive positions in response to radiation to compensate for the irregularities in the characteristics of the articles in the closed container at the progressive positions.

47. In a combination as set forth in claim 46 wherein

the irregularities in the characteristics of the articles and in the fixtures provide irregularities in the response of the articles and the fixtures to radiation.

48. In a combination as set forth in claim 46,

a conveyor for moving the closed container and the fixture in a first direction, and

a source of radiation disposed relative to the closed container and the fixture for irradiating the articles in the closed container and the fixture in a second direction substantially perpendicular to the first direction.

49. In a combination as set forth in claim 46 wherein

the fixture is made from a material selected from a group consisting of a plastic and a metal and having substantially the same characteristics per unit of distance of absorbing irradiation as the articles in the closed container.

50. In a combination as set forth in claim 48 wherein

the irregularities in the characteristics of the articles and in the fixtures provide irregularities in the absorption of radiation of the articles and the fixtures to radiation.

51. In a combination as set forth in claim 46,

a conveyor for moving the closed container and the fixture in a first direction, and

a source of radiation disposed relative to the closed container and the fixture for irradiating the articles in the closed container and the fixture in a second direction substantially perpendicular to the first direction.

52. In a combination as set forth in claim 47 wherein

the fixture is made from a material selected from a group consisting of a plastic and a metal and having substantially the same characteristics of absorbing radiation as the articles in the closed container.

Evidence Appendix

None.

Related Proceeding Appendix

None.